

## Wezlana

Saudi Arabia · access guide

# How to access Wezlana from Saudi Arabia, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A patient in the Saudi Arabia with moderate-to-severe plaque psoriasis, psoriatic arthritis, Crohn's disease, or ulcerative colitis may receive a prescription for Wezlana (ustekinumab-auub) from their treating dermatologist, rheumatologist, or gastroenterologist. Wezlana is the first FDA-approved biosimilar to Stelara (the reference ustekinumab), developed by Amgen and approved for the same indications as the reference product with an interchangeability designation in the US. In Saudi Arabia, biosimilar availability in hospital pharmacies is growing but uneven; for families whose physicians want to begin on a specific biosimilar with US DSCSA-documented sourcing, a named-patient import pathway is a clean route.

This guide explains the pathway, biosimilar positioning, documentation your physician prepares, indicative timing and cost bands, and where Reserve Meds fits in.

## The clinical situation

Wezlana is a fully FDA-approved biosimilar to the reference ustekinumab, meaning the FDA reviewed analytical, functional, and clinical comparability data and determined no clinically meaningful differences from Stelara in safety, purity, or potency. With its interchangeability designation, US pharmacists may substitute Wezlana for the reference product subject to state rules. Mechanism (IL-12/23 p40 blockade) and indications (plaque psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis) match the reference. SC maintenance dosing at 45 or 90 mg every 12 weeks after SC loading (or every 8 weeks after IV induction for IBD) is the standard pattern; your physician maps the sequence. Baseline TB screening, hepatitis panel, and infection-risk assessment apply as for the reference product.

## Is Wezlana legally importable into Saudi Arabia?

Yes, through the Ministry of Health and Prevention (SFDA) named-patient / personal-use import framework. The mechanism permits a Saudi Arabia-licensed physician, or the importing patient under a physician's prescription, to import a medicine not locally registered or not stocked when (a) the medicine is approved by a recognised reference authority such as the US FDA or EMA, (b) no clinically equivalent locally available option meets the patient's needs, (c) the physician accepts clinical responsibility, and (d) chain of custody is documented end to end. Biosimilars approved by the FDA fall squarely within this framework.

## How the pathway works, step by step

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1. **Consultation with your treating physician.** Diagnosis and severity documentation, prior therapy history, and the rationale for selecting a biosimilar (cost-effectiveness, availability, or specific product experience).
2. **Baseline screening.** Latent TB, hepatitis, and infection screening per labeling; baseline CBC and liver function.
3. **SFDA named-patient application.** Your physician or a Saudi Arabia hospital pharmacy files the application with clinical rationale, patient reference, product details, and chain-of-custody plan. For personal-use imports, the patient may file with supporting physician letter.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Wezlana from authorised distribution under DSCSA.
5. **Cold-chain shipment.** Wezlana ships under validated 2-8 °C conditions with temperature logging and chain-of-custody documentation.
6. **Arrival and administration.** IV induction for IBD at a Saudi Arabia hospital infusion centre; SC maintenance administered under physician supervision or, after training, at home.

## What documentation your physician needs

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- Clinical rationale letter confirming diagnosis, severity, and Wezlana (or ustekinumab-class) as the indicated therapy
- Verification of Saudi Arabia medical licence (DHA / DOH / SFDA as applicable)
- Severity assessment (PASI, Mayo, CDAI, or equivalent)
- Latent-TB and hepatitis screening results
- Planned dosing schedule
- Patient identifier (anonymised reference preferred)

Reserve Meds provides a physician documentation kit that bundles the templates SFDA reviewers expect to see for biosimilar named-patient imports, including biosimilar-specific product identifiers (non-proprietary name with the four-letter suffix).

## Typical costs and indicative timing

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Wezlana's US cash-pay drug-only reference range in 2026 sits at a meaningful discount to the reference ustekinumab, a broad indicative range of roughly USD 10,000-14,000 per 90 mg SC syringe, depending on the contracting channel. Biosimilar pricing is evolving and specific to the purchase window. International cold-chain logistics, SFDA documentation handling, customs, and concierge coordination are quoted separately. Reserve Meds issues a full transparent delivered quote at intake. Indicative range.

Indicative timing for first dose after cohort intake opens is 7-14 days from the moment a complete application is in hand. Maintenance refills ship on the every-8 or every-12-week cadence set by your physician.

*Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.*

## Where Reserve Meds fits in

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Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Wezlana specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from authorised channels.
- **Documentation.** Regulatory package for your physician and SFDA review, including biosimilar identifier language.
- **Logistics.** Validated 2-8 °C cold-chain shipment with temperature logging.
- **Concierge case lead.** A named point of contact coordinating induction, maintenance refills, and any dose-schedule adjustments.

**What we do not do:** we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating physician.

## Frequently asked

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**Is this legal in Saudi Arabia?** Yes, when executed through the SFDA named-patient / personal-use framework with appropriate documentation. See our trust and compliance page for our methodology.

**Is Wezlana the same as Stelara?** Wezlana is an FDA-approved biosimilar to Stelara with an interchangeability designation. That means the FDA has reviewed comparability evidence and found no clinically meaningful differences. Mechanism and indications match. The two products are not identical molecules but are therapeutically equivalent under FDA standards.

**Why switch to or start on Wezlana rather than the reference?** Patients and physicians typically choose the biosimilar for cost-effectiveness or supply availability. The clinical profile is expected to be equivalent; your physician discusses the specific switch or start rationale with you.

**Can I switch mid-course from Stelara to Wezlana?** Interchangeability means substitution is clinically supported. Your physician makes the decision and documents it; we can supply whichever product is prescribed.

**Will private insurance cover this?** Cash-pay is the default. Some Saudi Arabia private insurers consider named-patient imports case by case; we supply documentation for your submission but do not process claims directly.

### *Reserve Meds's role*

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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### Reserve Meds

*reserved for you.*

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.  
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